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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,821	04/19/2001	Fatih M. Uckun	12152.77USD1	2823
23552	7590	04/07/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1656	
DATE MAILED: 04/07/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/838,821

Applicant(s)

UCKUN, FATIH M.

Examiner

Hope A. Robinson

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 10, 2006 has been entered.
2. Applicant's response to the Office Action mailed August 10, 2005 on January 10, 2006, is acknowledged.
3. Claims 1-15 have been canceled. Claims 16-25 have been added. Claims 16-25 are pending and are under examination.

Withdrawn-Specification Objections

4. Previous objection to the specification are withdrawn by virtue of submission of an amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 22-25 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 22 and the dependent claims hereto are indefinite for the recitation of "treating or preventing a pathological condition", because the word "preventing" means to stop or avoid, however, the claimed invention might be effective in reducing occurrence of the condition but not complete cessation, thus, preventing should be deleted from the claim.

Withdrawn-Claim Rejections - 35 USC § 102

6. Previous rejection to claims under 35 U.S.C. 102 is withdrawn based on the amendments submitted.

Maintained-Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ihle et al. (WO 95/03701, February 9, 1995) in view of Narla et al. (Clinical Cancer Research, vol. 4, pages 1405-1414, June 1998) and Chae et al. (Cancer Research, vol. 53, pages 447-1151, February 1, 1993).

Ihle et al. teach a method to inhibit the activity of Janus family of kinase including JAK-3 (abstract, page 11 and claims 1-9 of the reference). The method taught by Ihle et al. is performed *in vitro* (page 16) and uses a protein to inhibit the activity of JAK-3 (abstract and page 21,). The reference further teaches that the method uses mammalian, human and avian cells (pages 15 and 32). Ihle et al. also teach a therapeutic wherein the inhibitor of JAK-3 is administered (page 35). The method of Ihle et al. inhibits the activity of JAK-3, which is necessary to inhibit c-jun activation as recited in claim 16 of the instant application (and the instant specification on page 8 discloses that an inhibitor of Janus family kinase 3 (JAK-3) can be used to inhibit c-jun expression).

In-so-far-as Ihle et al. do not explicitly teach radiation induced activation of c-jun, Narla et al. disclose the quinazoline derivative 4(4'-hydroxyphenyl)-amino-6,7-dimethoxyquinazoline as an inhibitor of the EGF-R tyrosine kinase (see page 1405, footnote 2 and 1409, col. 2, first paragraph) and Chae teach that protein tyrosine kinase activation precedes and perhaps mandates radiation induced activation of c-jun proto-oncogene expression in a human/mammalian cell (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole because Ihle et al. teach a method to inhibit the activity of JAK-3 which is necessary to inhibit c-jun activation as recited in claim 1 of the instant application (and the instant specification on page 8 discloses that an inhibitor of Janus family kinase 3 (JAK-3) can be used to inhibit c-jun expression) and Narla et al. teaches an inhibitor of protein tyrosine kinases which in turn inhibits c-jun and Chae teach that ionizing radiation increases the level of c-jun transcripts, thus activates c-jun. One of ordinary skill in the art would be motivated to

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combine the teachings of the references because it is known in the prior art that c-jun plays a role in cell proliferation; and the specification states that alterations of c-jun proto-oncogene expression can modulate the transcription of several growth-regulators affecting cell proliferation and differentiation (page 2). Moreover, the combined teachings of the reference indicates that c-jun expression is elevated in response to stimuli such as growth factors, cytokines and UV radiation and inhibited by quinazolines an inhibitor of JAK-3. Thus, the claimed invention is *prima facie* obvious.

Response to Arguments

8. The response filed on January 10, 2006 has been considered, however, is not fully persuasive. Note that a new ground of rejection has been instituted under 35 U.S.C. 112, second paragraph for the reasons stated above. Regarding the rejection maintained under 35 U.S.C. 103, applicant on page 6 of the amendment state that the primary reference is cited as teaching a method to inhibit JAK-3 which fails to teach or suggest a method for inhibiting the proto-oncogene, c-jun, using an inhibitor of JAK-3. It is further stated that the secondary reference does not cure the deficiencies of the primary reference. This argument is not persuasive because the primary reference, Ihle et al. remain relevant to the claimed invention. The claimed method inhibits c-jun indirectly by inhibiting JAK-3. Cells are contacted with a JAK-3 inhibitor and the resulting effect is inhibition of c-jun activation. Although the method of the reference by Ihle et al. does not explicitly teach inhibition of c-jun, they disclose a method to inhibit JAK-3, which will result in inhibition of c-jun. Inhibition of c-jun activation is a resultant effect of contacting cells with an inhibitor of JAK-3. Ihle et al. has a method to inhibit the activity of JAK-3 and a

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therapeutic wherein an inhibitor of JAK-3 is administered, the resulting effect must necessarily be inhibition of c-jun, thus, intrinsically an inhibition method for c-jun activation. "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing."; see *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

Applicant is claiming an invention employing the **same process steps** but the objective of the process is **alleged to be different**. Applicant is required to recite the missing steps to formulate the alleged differences in view of the above cited decision. Additionally, the secondary reference by Narla et al. teach a quinazoline derivative which are recognized in the art as inhibitors of JAK-3 and Chae teach that ionizing radiation increases the level of c-jun transcripts, thus activates c-jun. Furthermore, claim 14 only requires that "c-jun activation is implicated". Thus, the claimed invention is prima facie obvious and the rejection remains. Therefore, the rejection remains.

Conclusion

9. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957.

The examiner can normally be reached on Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner

[Handwritten signature]
11/3/04

**HOPE ROBINSON
PATENT EXAMINER**